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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,771	03/23/2005	Ikuya Seki	Q86824	2031

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/528,771	SEKI ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 10-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7 and 10-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the directives of the response filed 2/17/06, claims 1, 2, 4-7, 10-14 have been amended, and claim 15 added. Claims 1, 2, 4-7, 10-15 are now pending.

Applicants' species elections are acknowledged.

✧

Objection is raised to the abstract. The abstract contains grammatical errors; these are most likely evident to applicants' counsel.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 10-13 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is drawn to a compound that is labeled with a radioactive metal or a paramagnetic metal. However, it is not apparent where in the specification this is described. Note that the issue here pertains to that of a compound versus a composition. It may very well be the case that there is descriptive support for a composition that contains a compound of claim 1 which is complexed to a metal

ion. But a single, pure compound is another matter entirely. Applicants are requested to point to the relevant page and line number.

✧

Claims 5, 6, 10-13 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 is drawn to a compound that is labeled with a metal. The issue here is that the specification does not teach how to make a single, pure compound that is labeled with a radioactive metal or a paramagnetic metal. It is stipulated that the specification discloses how to make a composition that comprises a compound to which is complexed a metal ion or metal oxide. But that is not the issue which is being raised here. The issue pertains to that of a single, pure compound that is labeled with a radioactive metal or a paramagnetic metal. For example, a preferred composition disclosed in the specification (pages 45-46) is that which contains TcO^{4-}, glucoheptonic acid, $SnCl_2$, a peptide of claim 1, DMF, and water. However, this is a composition, not a compound. It is noted also that page 36 (line 2+) of the specification, there is mention of purification. However, there is no further explanation, or even an assertion of what is obtained. In traversing, it is suggested that applicants point to a specific composition that disclosed in the specification (which contains a metal

ion or metal oxide) and explain how it is that this is a single pure compound. Account should be taken of any counterions that might be present. Alternatively, applicants can abstain from asserting that a complex between an organic compound and a metal ion (or metal oxide) qualifies as a single, pure compound.

An issue unrelated to the foregoing concerns claim 13. This claim is drawn to a method of "radiotherapy". The first point is that the specification does not explain exactly what this means. No diseases are even suggested that would fall within the scope of this term. It is noted that various diseases are mentioned on page 4, line 22+ of the application, and on pages 32-34 (e.g., viral infection, autoimmune disease, colitis, glomerulonephritis). However, the specification stops short of even asserting that the claimed compounds will be effective to treat any of them. Thus, the first hurdle facing the skilled artisan (endeavoring to practice the claimed invention) would be to determine which diseases (if any) exist for which there is even a remote possibility of success in treating. As for experimental data, applicants have provided evidence that the compounds can be used for imaging. But that is not the issue here.

In addition to imaging experiments, applicants have also shown (pages 92-94) that representative compounds of the invention can bind to the N-formyl peptide receptor. However, applicants have not related this result to treatment of any particular disease. Nor have applicants explained what the role, if any, of the

Y^{90}, Sn^{117m}, Sm^{153}, Re^{186}, or Re^{188} ions (or oxides) might be. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Thus, in view of the total absence of guidance, the lack of working examples, and the absence of any supportive evidence from the prior art, it is evident that "undue experimentation" would be required to use the claimed compounds to achieve some sort of "radiotherapy".

✧

Claims 1, 2, 4-7, 10-15 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, the first line of text following the formula begins with "wherein in the formula". The word "wherein" is preceded by a parenthesis. Both the left parenthesis and the right parenthesis should be eliminated, since the definition of variables is critical to the claimed invention.

- In claim 1, clarity would be enhanced by beginning the definition of each substituent and integer variable on a new line, i.e., the following format:

  wherein

Z represents an amino protecting group
Y represents methionine or norleucine;
X represents a spacer consisting of ...
R represents serine or threonine which is bonded to the epsilon-amino group...
T represents a spacer consisting of...
U represents a group which...
l is an integer of 0 or 1;
n is an integer of 0 or 1;
m is an integer of 0 or 1;

- In claim 1, formula (1), the following is present: "$Lys(NH2)_m$" Here, the "2" should be a subscript.

- In claim 1, formula (1), the following is present: "(R-(T)l-U) Here, the "L" should be present as a subscript.

- Claim 5 is drawn to a compound that is labeled with a metal. However, claim 1, upon which claim 5 depends, makes no mention of a metal ion (or zerovalent metal or metal oxide). What is really intended in claim 5 is to describe a complex which is formed between the compound of claim 1, and a metal ion or metal oxide; in many cases a counterion (e.g., chloride or acetate) will be present. Accordingly, claim 5 is not properly dependent on claim 1, since claim 1 makes no allowance for metal ions or metal oxides, and moreover is drawn to a single, pure compound, rather than a composition or a complex. It is suggested that claim 5 be cast in independent form.

- As indicated above, claim 5 is drawn to a "compound" that is labeled with a metal. However, it does not appear that there are any examples in the specification of a metal-bearing compound. No doubt there are examples of compositions which contain both a metal ion and a compound of claim 1, but that is not the issue. The issue here is largely semantic. For example, a preferred composition disclosed in the specification (pages 45-46) is that which contains TcO^{4-}, glucoheptonic acid, $SnCl_2$, a peptide of claim 1, DMF, and water. In applicants opinion, exactly what component of this mixture would correspond to a single, pure compound of claim 5...? In answering, applicants should specify the valency of the

technetium and the atoms to which the technetium is bonded.... this will facilitate further discussion.

- In claim 6, the "u" in "CU-64" should be lowercase.
- In claim 7, the terms "SPECT" and "PET" may be used, if accompanied by an explanation of what these acronyms represent.
- Claim 13 is indefinite as to the objectives of the radiotherapy.

✦

The two journal articles (Edwards, 1999 and Verbeke, 2000) were stricken from the IDS because they were not received.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER